UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

WALGREEN CO., THE KROGER CO., ALBERTSONS COMPANIES, INC. and H-E-B, L.P., Plaintiffs, vs. ASTRAZENECA PHARMACEUTICALS L.P., ASTRAZENECA L.P., ASTRAZENECA UK LIMITED, HANDA PHARMACEUTICALS, LLC, PAR PHARMACEUTICAL, INC. and ACCORD HEALTHCARE, INC., Defendants.	CASE NO. JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Albertsons Companies, Inc. and H-E-B, L.P. ("Plaintiffs") sue Defendants AstraZeneca Pharmaceuticals L.P., AstraZeneca L.P., AstraZeneca UK Limited (collectively, "AstraZeneca"), Handa Pharmaceuticals, LLC ("Handa"), Par Pharmaceutical, Inc. ("Par") and Accord Healthcare, Inc. ("Accord") for Defendants' violations of the antitrust laws concerning the pharmaceutical drug Seroquel XR. For their Complaint, Plaintiffs allege as follows:

I. NATURE OF THE ACTION

1. This is a Civil antitrust Action seeking treble damages and other relief arising out of Defendants' foreclosure of generic competition to Seroquel XR, a prescription drug approved by the U.S. Food and Drug Administration ("FDA") in the United States to treat certain mental health disorders. Seroquel XR is approved as: (1) an add-on treatment to an antidepressant for patients with major depressive disorder who did not have an adequate

response to antidepressant therapy; (2) treatment for acute depressive episodes in bipolar disorder; (3) treatment for acute manic or mixed episodes in bipolar disorder alone or with lithium or divalproex; (4) long-term treatment of bipolar disorder with lithium or divalproex; and (5) treatment for schizophrenia. Plaintiffs seek overcharge damages arising from AstraZeneca's unlawful agreements with Handa and Accord not to compete in the market for Seroquel XR and corresponding generic versions thereof in the United States. As set forth below, Handa subsequently assigned its unlawful agreement with AstraZeneca to Par, which performed the agreement, sold generic Seroquel XR at supracompetitive prices, and shared the illicit gains with Handa.

2. Prior to the market entry of generic versions of Seroquel XR, AstraZeneca's U.S. sales of branded Seroquel XR exceeded $1 billion annually.

3. Generic manufacturers Handa and Accord recognized the huge market potential for generic versions of Seroquel XR and, between June and December of 2008, each filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market certain strengths of generic extended-release quetiapine fumarate tablets. Handa was the first generic drug maker to submit an ANDA (No. 90-482) for the 50 mg, 150 mg, 200 mg and 300 mg strengths of extended-release quetiapine fumarate tablets, with Seroquel XR as its Reference Listed Drug. On June 18, 2008, Accord was the first generic drug maker to file an ANDA (No. 90-681) for the 400 mg strength of extended-release quetiapine fumarate tablets, with Seroquel XR as the Reference Listed Drug. Handa thereafter filed an ANDA for the 400 mg strength.

4. Pursuant to 21 U.S.C. § 355(j)(2)(B), Handa sent AstraZeneca four separate Paragraph IV notice letters dated July 10, 2008, July 23, 2008, October 16, 2008, and November 14, 2008. Accord sent AstraZeneca two separate Paragraph IV notice letters dated

September 5, 2008 and January 23, 2009. In the Paragraph IV notice letters, Handa and Accord each certified that they would seek final FDA approval to market, and intended to launch, their generic Seroquel XR products prior to the expiration of the follow-on patent purportedly covering Seroquel XR, U.S. Patent No. 5,948,437 (the "'437 Patent"), which Handa and Accord claimed was invalid and/or would not be infringed by Handa's and Accord's respective proposed generic Seroquel XR products.

5. The '437 Patent expired on May 28, 2017. The regulatory exclusivities associated with the '437 Patent expired on November 28, 2017.

6. On July 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 200 mg, 300 mg and 400 mg strengths of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).

7. On October 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 50 mg strength of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).

8. On December 8, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 150 mg strength of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).

9. AstraZeneca's three lawsuits against Handa were consolidated, and are collectively referred to herein as the "Handa Seroquel XR Patent Litigation."

10. AstraZeneca filed two patent infringement lawsuits against Accord regarding the two Accord Paragraph IV certification notice letters. First, on September 26, 2008,

AstraZeneca filed Civil Action No. 08-cv-04804 against Accord in the District of New Jersey in connection with Accord's notice letter dated September 5, 2008. Second, on February 10, 2009, AstraZeneca filed Civil Action No. 09-cv-00619 against Accord in the District of New Jersey in connection with Accord's notice letter dated January 23, 2009. These lawsuits against Accord are collectively referred to as the "Accord Seroquel XR Patent Litigation."

11. Over the course of the Handa Seroquel XR Patent Litigation, it became clear that Handa's proposed generic version of Seroquel XR would not infringe the '437 Patent. The '437 Patent did not broadly claim the chemical compound quetiapine, or even its salt quetiapine fumarate. Instead, the '437 Patent narrowly claimed very specific formulations of quetiapine fumarate, each of which requires a "gelling agent." The Honorable Joel A. Pisano, who presided over the Accord Seroquel XR Litigation and the Handa Seroquel XR Patent Litigation, construed "gelling agent" to mean "any substance which forms a gel when in contact with water." But Handa's proposed generic version of Seroquel XR used hydrogenated vegetable oil, which could not be a "gelling agent" under the district court's claim construction. Hydrogenated vegetable oil is hydrophobic, and not even miscible with water, *i.e.*, it does not form a homogeneous mixture with water.

12. The District Court issued its claim construction opinion applicable in both the Handa Seroquel XR Patent Litigation and the Accord Seroquel XR Patent Litigation on November 30, 2010.

13. On December 9, 2010, the FDA granted tentative approval to Handa's ANDA for generic Seroquel XR in all strengths, determining that Handa's ANDA for generic Seroquel XR was approvable and satisfied all requirements for bioequivalence; chemistry, manufacturing, and controls ("CMC"); and labeling.

14. Under the District Court's claim construction, AstraZeneca was very likely to lose the '437 Patent litigation. Rather than face the risk that Handa's proposed generic versions of Seroquel XR would be found not to infringe the '437 Patent, AstraZeneca induced Handa with a large "reverse payment" to abandon the patent fight and agree not to compete with AstraZeneca for up to five years. Such payments are referred to as "reverse payments" because the patent holder pays the alleged infringer, whereas ordinarily the alleged infringer would pay the patent holder to settle patent litigation.

15. Specifically, on or about September 29, 2011, AstraZeneca and Handa entered into a settlement agreement concerning Handa's ANDA No. 90-482 (the "Handa Non-Compete Agreement"). Under the terms of the Handa Non-Compete Agreement, Handa agreed to abandon the patent fight and delay its launch of generic extended-release quetiapine fumarate in the 50 mg, 150 mg, 200 mg and 300 mg strengths until November 1, 2016 (and also agreed to quit the patent fight as to the 400 mg strength as well, for which Handa was not the first filer). In exchange for Handa's delayed generic launch, AstraZeneca agreed not to compete with Handa by launching an authorized generic Seroquel XR (the brand product packaged and sold as a generic, sometimes referred to as an "AG") during the first 180 days after Handa's launch, *i.e.*, between November 1, 2016 and April 30, 2017. But for the Handa Non-Compete Agreement, Handa would not have agreed to delay the 50 mg, 150 mg, 200 mg, 300 mg strengths of generic Seroquel XR until November 1, 2016 and AstraZeneca would not have agreed to delay an authorized generic in these strengths to compete with Handa's generic product until May 1, 2017. The purpose and effect of the Handa Non-Compete Agreement was to delay lower- priced generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG in the 50 mg, 150 mg, 200 mg, 300 mg strengths during Handa/Par's 180-

day period of generic exclusivity (as described below), thereby generating enormous windfalls for AstraZeneca and Handa (and eventually Par).

16. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90-482. Par's press release stated that it:

> entered into an exclusive acquisition and license agreement with Handa Pharmaceuticals, LLC to acquire Handa's Abbreviated New Drug Application (ANDA) for quetiapine fumarate extended-release tablets, the generic version of AstraZeneca's Seroquel XR®. Handa believes it is the first applicant to file an ANDA containing a paragraph IV certification for the 50 mg, 150 mg, 200 mg and 300 mg strengths of the product, which would potentially provide 180 days of marketing exclusivity . . . .
>
> Under the terms of the agreement, Par has made a payment for the ANDA and for exclusive rights to market, sell and distribute quetiapine fumarate extended-release tablets in the U.S. under the ANDA, subject to its final approval by the U.S. Food and Drug Administration. Par will receive a share of profits from the sales of the product. Under the terms of a prior settlement agreement with AstraZeneca, which has been assigned to Par, Par has a license to enter the U.S. market with quetiapine fumarate extended-release tablets on November 1, 2016 or earlier under certain circumstances.

17. A press release that Handa issued on May 10, 2017 confirms that Handa and Par agreed, as part of their acquisition and license agreement, to share in the illicit profits from their Handa Non-Compete Agreement. The press release states, "Par's Quetiapine XR ANDA was developed by Handa and acquired by Par on August 3, 2012. Handa retains the right to a portion of profits from the sale of the product, pursuant to its agreement with Par." By acquiring Handa's ANDA, acquiring an assignment of the Handa Non-Compete Agreement, agreeing to divide the illicit gains therefrom, performing the delay provisions thereof, and selling generic Seroquel XR at supracompetitive prices, Par became an active participant and co-conspirator in the pre-existing conspiracy between Handa and AstraZeneca. Accordingly like Handa and AstraZeneca, Par is jointly and severally liable for all harm flowing from the conspiracy.

18. Accord and AstraZeneca entered into an agreement similar to the Handa Non-Compete Agreement, which included a similar reverse payment from the patent holder, AstraZeneca, to the alleged infringer, Accord, to abandon the patent fight and agree not to compete with AstraZeneca for up to five years. Specifically, on or about October 5, 2011, prior to the end of any trial, Accord and AstraZeneca entered into an agreement pursuant to which Accord agreed to delay its launch of the 400 mg strength of generic Seroquel XR, for which Accord was the first ANDA filer, until November 1, 2016, and AstraZeneca agreed not to launch an authorized generic version of the 400 mg strength for 180 days thereafter. Pursuant to this agreement, Accord in fact did not launch generic 400 mg Seroquel XR until November 1, 2016, and AstraZeneca did not launch an authorized generic version of Seroquel XR 400 mg until May 1, 2017. The Accord-AstraZeneca settlement agreement is referred to as the "Accord Non-Compete Agreement."

19. But for the Accord Non-Compete Agreement, Accord would not have agreed to delay 400 mg generic Seroquel XR until November 1, 2016 and AstraZeneca would not have agreed to delay launching an authorized generic in this strength to compete with Accord's generic product until May 1, 2017. The purpose and effect of the Accord Non-Compete Agreement was to delay lower-priced generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG during Accord's 180-day period of generic exclusivity, thereby generating enormous windfalls for AstraZeneca and Accord.

20. On November 1, 2016, Par began selling 50 mg, 150 mg, 200 mg and 300 mg generic Seroquel XR and Accord began selling 400 mg generic Seroquel XR.

21. On May 1, 2017 (180 days later), AstraZeneca launched authorized generic versions of Seroquel XR in the 50 mg, 150 mg, 200 mg, 300 mg, and 400 mg strengths.

22. Several other generic competitors launched their own versions of generic Seroquel XR (in all strengths) in or around early May 2017.

23. Because of the unlawful Handa Non-Compete Agreement and Accord Non-Compete Agreement (together, the "Non-Compete Agreements"), no generic Seroquel XR was available for purchase in the United States until November 1, 2016 and, for a period of six months thereafter, only one generic was available for each strength of Seroquel XR (marketed by Par in the 50 mg, 150 mg, 200 mg, and 300 mg strengths and by Accord in the 400 mg strength).

24. But for the unlawful Non-Compete Agreements, one or more generic versions of Seroquel XR (in each strength) would have entered the market much earlier – either following patent litigation victory by Handa and/or Accord, at-risk launch(es) by Handa and/or Accord, or agreement(s) that did not include unlawful reverse payments from AstraZeneca for delay. Courts have repeatedly recognized that payments for delay result in later generic entry dates. *See, e.g., In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014). In addition, AstraZeneca would have simultaneously launched authorized generic Seroquel XR (in each strength) when generic entry occurred instead of waiting until after Handa/Par's and Accord's 180-day marketing exclusivity lapsed (as AstraZeneca actually did). Thus, absent the unlawful Non-Compete Agreements, Plaintiffs would have been able to satisfy their requirements for extended-release quetiapine fumarate at significantly lower prices substantially earlier.

25. By means of the Non-Compete Agreements, AstraZeneca, Handa/Par and Accord agreed to divide ill-gotten revenues, both during the period in which Handa/Par and Accord agreed not to launch (*i.e.*, prior to November 1, 2016), and during Handa/Par's and Accord's 180-day periods of generic marketing exclusivity during which AstraZeneca agreed

not to launch authorized generic Seroquel XR to compete with Handa/Par's and Accord's respective generic products, all of which resulted in anticompetitive overcharges to Plaintiffs.

26. Defendants violated Sections 1 and 2 of the Sherman Act through the anticompetitive Non-Compete Agreements that allocated markets, restricted output, and improperly maintained, enhanced and extended AstraZeneca's market and monopoly power by (1) foreclosing or delaying competition from lower-priced generic Seroquel XR that otherwise would have entered the market earlier; (2) foreclosing or delaying competition from authorized generic Seroquel XR that otherwise would have entered the market earlier; and (3) fixing, raising, maintaining, or stabilizing the prices of Seroquel XR and its generic equivalents at supracompetitive levels.

27. Plaintiffs were injured and sustained damages in the form of overcharges on purchases of both branded and generic forms of Seroquel XR as a direct result of the unlawful Non-Compete Agreements.

II. PARTIES

28. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Seroquel XR, to the public. Walgreen brings this Action in its own behalf and as the assignee of Amerisource-Bergen Drug Corporation, a pharmaceutical wholesaler, which during the relevant period purchased Seroquel XR directly from Defendants for resale to Walgreen and which has expressly assigned its claims arising out of those purchases to Walgreen.

29. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Seroquel XR, to the

public. Kroger brings this Action in its own behalf and as the assignee of Cardinal Health, Inc., a pharmaceutical wholesaler, which during the relevant period purchased Seroquel XR directly from Defendants for resale to Kroger and which has expressly assigned its claims arising out of those purchases to Kroger.

30. Plaintiff Albertsons Companies, Inc. ("Albertsons") is a Delaware corporation having its principal place of business at 250 Parkcenter Boulevard, Boise Idaho 83706. Albertsons' affiliates own and operate retail stores in several states at which they dispense prescription drugs, including Zetia, to the public. Albertsons brings this Action in its own behalf and as the assignee of McKesson Corporation ("McKesson"), a pharmaceutical wholesaler, which during the relevant period purchased Zetia directly from Merck for resale to Albertsons' subsidiaries and which has expressly assigned its claim arising out of those purchases to Albertsons.

31. Plaintiff H-E-B L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores at which it dispenses prescription drugs, including Zetia, to the public. HEB brings this Action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Zetia directly from Merck for resale to HEB and which has expressly assigned its claims arising out of those purchases to HEB.

32. Defendant AstraZeneca Pharmaceuticals L.P. is a limited partnership organized under the laws of Delaware, with a principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

33. Defendant AstraZeneca L.P. is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

34. Defendant AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN.

35. Defendant Handa Pharmaceuticals, LLC is a limited liability corporation organized under the laws of California, with a principal place of business at 1732 N. 1st Street, Suite 200, San Jose, California 95112.

36. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

37. Defendant Accord Healthcare, Inc. is a North Carolina corporation with its principal place of business at 1009 Slater Road, Suite 210, Durham, North Carolina 27703.

38. All of Defendants' Actions described in this Complaint were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with Defendants' actual and/or apparent authority.

III. JURISDICTION AND VENUE

39. This Action is brought pursuant to section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover treble damages and the costs of suit, including reasonable attorneys' fees, for injuries sustained by Plaintiffs as a result of Defendants' violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. This Court's jurisdiction is based upon 28 U.S.C. §§ 1331 and 1337(a).

40. Defendants are found and transact business within this judicial district, and Defendants' interstate trade and commerce hereinafter described was carried out, in substantial

part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

41. This Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal conduct and conspiracy throughout the United States, including in this District. The conduct and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. REGULATORY BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

42. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

43. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Seroquel XR, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection.

The patient (and in most cases his or her insurer) is obligated to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

44. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

45. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

46. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

47. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within thirty days of their issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

48. The FDA relies completely on the brand manufacturer's representations about patent validity and applicability, as it does not have the resources or authority to verify the validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

49. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. It must only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug. In other words, the ANDA must demonstrate that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically

equivalent") to the brand drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

50. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

51. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

52. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had increased many-fold to $300 billion.

D. Paragraph IV Certifications

53. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III

certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

54. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement Action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

55. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to

50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

56. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity. This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

E. Benefits of Generic Drugs

57. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as Plaintiffs, a generic typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies, such as AstraZeneca, view competition from generic drugs as a grave threat to their bottom lines.

58. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute

generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

59. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

60. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the agreement at issue here.

F. The Impact of Authorized Generics

61. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period pursuant to its own approved NDA. Such an "authorized generic" is literally identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both the ANDA filer's generic drug and the authorized generic and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

62. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission found that authorized generics capture a

significant portion of sales, reducing the revenues generated by the first-filer's generic product by approximately 50% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

63. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

64. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their brand drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the brand drug at the same rate at which it was raised prior to generic entry.

65. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such agreements deprive drug purchasers such as Plaintiffs of the lower prices resulting from two forms of competition. During the initial period of delay agreed to by the ANDA filer, they effectively eliminate all competition from AB-rated generic products and allow the brand manufacturer to preserve its monopoly. And, during the period in which the branded company has agreed not to sell an

authorized generic, they eliminate competition between the ANDA filer's generic and the authorized generic, giving the ANDA filer a monopoly on generic sales.

66. As a means of compensating first-filing generic manufacturers, brand manufacturers prefer no-AG agreements to cash payments because, in the case of no-AG agreements, a portion of the compensation is paid by purchasers of the drug in the form of higher generic drug prices. The generic manufacturer receives not only the profits that the brand manufacturer would have made by launching an authorized generic in competition with the ANDA filer's product, but also the higher prices that result from the absence of that competition. Thus, the payment to the generic manufacturer is shared between the brand manufacturer and the generic manufacturer's customers.

V. OPERATIVE FACTS

A. AstraZeneca's Seroquel XR Patents

67. AstraZeneca Pharmaceuticals L.P. is the holder of NDA No. 22-047, under which the FDA granted approval for extended-release tablets containing various different dosage strengths of the active ingredient 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f] [1,4] thiazepine fumarate, which is commonly referred to as quetiapine fumarate. AstraZeneca Pharmaceuticals LP markets these tablets in the United States under the trademark Seroquel® XR.

68. AstraZeneca Pharmaceuticals L.P. is the owner of U.S. Patent No. 4,879,288 ("the '288 Patent"). The '288 Patent issued on November 7, 1989 from United States Application No. 07/028,473, which was filed on March 20, 1987. Although the '288 Patent was originally set to expire on March 20, 2007, it received a patent term extension ("PTE") of 1,651 days under 35 U.S.C. § 156. Based upon the PTE, the '288 Patent expired on September 26, 2011.

69. AstraZeneca UK Limited is the owner of the '437 Patent. The '437 Patent issued on September 7, 1999 from United States Application No. 08/864,306, which was filed on May 28, 1997. The '437 Patent expired on May 28, 2017.

70. AstraZeneca submitted the '288 and '437 Patents for listing in the FDA Orange Book under NDA No. 22-047. AstraZeneca Pharmaceuticals LP received pediatric exclusivity for NDA No. 22-047, and the pediatric exclusivity associated with the '288 and '437 Patents expired on March 26, 2012 and November 28, 2017, respectively.

71. Because the '288 Patent expired on September 26, 2011 and its pediatric exclusivity expired on March 26, 2012, neither the '288 Patent nor its associated pediatric exclusivity could have affected any generic drug company's right, ability or willingness to market a generic version of Seroquel XR after March 26, 2012.

72. The '437 Patent contains one independent claim and fourteen dependent claims. Independent claim 1 recites

> A sustained release formulation comprising a gelling agent and 11-[4-[2-(2-hydroxyethoxy) ethyl]-1-piperazinyl]dibenzo-[b,f][1,4]-thiazepine or a pharmaceutically acceptable salt thereof, together with one or more pharmaceutically acceptable excipients.

Each of the fourteen dependent claims in the '437 Patent incorporates the requirements of claim 1, including the requirement for a "gelling agent." "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Accordingly, no generic drug company's ANDA or generic drug product could infringe the '437 Patent unless it contained, *inter alia*, a "gelling agent" as claimed in the '437 Patent.

B. Handa and Accord File ANDAs for Generic Versions of Seroquel XR

73. Handa and Accord were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Seroquel XR patents.

74. Handa filed ANDA No. 90-482 for a generic version of extended-release quetiapine fumarate. Between spring and fall of 2008, Handa amended its ANDA four times. Handa was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 50 mg, 150 mg, 200 mg, and 300 mg strengths. As a result, it was eligible for 180 days of regulatory exclusivity for those strengths of generic Seroquel XR. Handa's ANDA also included a Paragraph IV certification for the 400 mg strength, although Handa was not the first applicant to file a substantially complete application containing a Paragraph IV certification for the 400 mg strength.

75. Accord filed ANDA No. 90-681 for a generic version of extended-release quetiapine fumarate on June 18, 2008. Accord was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 400 mg strength of extended-release quetiapine fumarate. As a result, Accord was eligible for 180 days of regulatory exclusivity for that strength of generic Seroquel XR.

76. Because Handa and Accord were the first generic companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. § 355(j)(5)(B)(iv): 180-days of marketing exclusivity during which the FDA would not grant final approval to any other ANDA for generic Seroquel XR.

77. After receiving confirmation of receipt from the FDA for their ANDAs, Handa sent four separate Paragraph IV notice letters to AstraZeneca of its ANDA. Each included a detailed statement of the factual and legal basis as to why the '437 Patent was invalid,

unenforceable, and/or not infringed by Handa's ANDA products. The Paragraph IV notice letters included an offer of confidential access to Handa's ANDA as required under the Hatch-Waxman Act. The notice letters were dated July 10, 2008, July 23, 2008, October 16, 2008, and November 14, 2008. The notice letters gave rise to an artificial act of infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of Action for infringement against Handa under the Hatch-Waxman Act (if AstraZeneca otherwise had a basis to sue under Rule 11).

78. Similarly, Accord sent AstraZeneca two separate Paragraph IV notice letters dated September 5, 2008 and January 23, 2009. Accord's Paragraph IV certifications were required by statute to include "a detailed statement of the factual and legal basis of the opinion of the applicant that ['437 Patent] is invalid or will not be infringed," by Accord's generic Seroquel XR products. Accord's Paragraph IV notice letters also included an offer of confidential access to Accord's ANDA as required under the Hatch-Waxman Act. The notice letters gave rise to an artificial act of infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of Action for infringement against Accord under the Hatch-Waxman Act (if AstraZeneca otherwise had a basis to sue under Rule 11).

C. The Seroquel XR Patent Litigation

79. AstraZeneca filed three patent infringement lawsuits against Handa in response to Handa's Paragraph IV certification notice letters. First, in response to Handa's notice letters dated July 10, 2008 and July 23, 2008, AstraZeneca filed Civil Action No. 08-cv-3773 in the District of New Jersey on July 28, 2008. Second, on October 28, 2008, AstraZeneca filed Civil Action No. 08-cv-5328 in the District of New Jersey in response to Handa's notice letter dated October 16, 2008. Third, on December 8, 2008, AstraZeneca filed Civil Action No. 08-cv-5997 in the District of New Jersey in response to Handa's notice letter dated November 14, 2008.

80. AstraZeneca filed two patent infringement lawsuits against Accord in response to Accord's Paragraph IV certification notice letters. First, on September 26, 2008, AstraZeneca filed Civil Action No. 08-cv-04804 against Accord in the District of New Jersey in response to Accord's notice letter dated September 5, 2008. Second, on February 10, 2009, AstraZeneca filed Civil Action No. 09-cv-00619 against Accord in the District of New Jersey in response to Accord's notice letter dated January 23, 2009.

81. Several generic drug companies in addition to Handa and Accord filed ANDAs seeking approval of generic versions of Seroquel XR ("the Later-Filing Generics"). AstraZeneca subsequently filed seven patent infringement lawsuits relating to generic Seroquel XR against four of the Later-Filing Generics in the District of New Jersey. On April 8, 2010, AstraZeneca filed Civil Action No. 10-cv-1835 against Anchen Pharmaceuticals, Inc. and Anchen, Inc. (together, "Anchen"). On August 16, 2010, AstraZeneca filed Civil Action No. 10-cv-4203 against Osmotica Pharmaceutical Corporation ("Osmotica"). Also on August 16, 2010, AstraZeneca filed Civil Action No. 10-cv-4205 against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, "Torrent"). On September 28, 2010, AstraZeneca filed Civil Action No. 10-cv-4971 against Torrent. On October 22, 2010, AstraZeneca filed Civil Action No. 10-cv-5519 against Mylan Pharmaceuticals, Inc. and Mylan, Inc. (together, "Mylan"). On April 29, 2011, AstraZeneca filed Civil Action No. 11-cv-2483 against Mylan. Also on April 29, 2011, AstraZeneca filed Civil Action No. 11-cv-2484 against Osmotica. The foregoing seven patent infringement lawsuits are referred to herein as "the Later-Filer Seroquel XR Patent Litigation."

82. The Handa Seroquel XR Patent Litigation, the Accord Seroquel XR Patent Litigation, and the Later-Filer Seroquel XR Patent Litigation are referred to collectively as "the Seroquel XR Patent Litigation."

83. During claim construction proceedings in the Seroquel XR Patent Litigation, the district court construed the term "gelling agent" as "any substance which forms a gel when in contact with water."[1]

84. The 30-month stay preventing final FDA approval of Handa's ANDA expired no later than April 2011. The 30-month stay preventing final FDA approval of Accord's ANDA expired no later than July 2011.

85. On or about September 29, 2011, as further described below, AstraZeneca reached a settlement with Handa resolving the Handa Seroquel XR Patent Litigation. As a result, some or all of Handa's defenses in the Handa Seroquel XR Patent Litigation were never adjudicated.

86. On or about October 5, 2011, AstraZeneca reached a settlement with Accord resolving the Accord Seroquel XR Patent Litigation. As a result, some or all of Accord's defenses in the Accord Seroquel XR Patent Litigation were never adjudicated.

87. AstraZeneca did not settle with the Later-Filing Generics prior to trial and the Later-Filer Seroquel XR Patent Litigation proceeded to a bench trial in October 2011. At the trial, three of the Later-Filing Generics – namely, Anchen, Osmotica, and Mylan – did not advance a non-infringement defense, in part because their generic version(s) of Seroquel XR used hydroxypropylmethylcellulose ("HPMC"), the "preferred gelling agent of the '437 patent":

> The proposed ANDA products of Anchen, Osmotica and Mylan Pharms contain HPMC, the preferred gelling agent of the '437 patent. Anchen, Mylan and Osmotica have not contested that their proposed ANDA products would infringe various claims of the '437 patent if those claims are not found to be invalid.[2]

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[1] *See AstraZeneca Pharm., LP v. Anchen Pharm., Inc.*, Civ. No. 10-cv-1835, 2012 WL 1065458, at *2 (D.N.J. Mar. 29, 2012).

[2] *See AstraZeneca Pharm., LP*, 2012 WL 1065458, at *8.

88. The generic Seroquel XR product of the fourth Later-Filing Generic – *i.e.*, Torrent – did not use HPMC but did use a "naturally-occurring hydrophilic polymer" sold under the brand name Viscarin 209 that "hydrates and swells in the presence of water."[3] The district court in the Later-Filer Seroquel XR Patent Litigation concluded that Viscarin 209 was indeed a "gelling agent" under the court's claim construction, and found that Torrent's generic Seroquel XR product infringed the '437 Patent.[4]

D. Handa's Unadjudicated Defenses Were Meritorious

89. Unlike the Later-Filing Generics, Handa successfully designed around the '437 Patent by developing a non-infringing product that did not contain as "gelling agent" as required by each of the claims of the '437 Patent. Instead of using a hydrophilic "gelling agent," Handa's products used a hydrophobic compound known as hydrogenated vegetable oil ("HVO"). Each of the Later-Filing Generics, in contrast, used hydrophilic compounds that formed gels when placed in contact with water. As explained below, Handa obtained a patent on its novel formulation despite the '437 Patent, reflecting the determination of the United States Patent and Trademark Office ("PTO") that Handa's formulation was patentably distinct from the formulation claimed in the '437 Patent.

90. On July 24, 2008, Handa filed United States Provisional Application No. 61/083,270 ("the '270 Application"). On September 5, 2008, Handa filed United States Application Serial No. 12/205,356 ("the '356 Application"), which claimed the benefit of the filing date of the '270 Application. On May 8, 2012, the '356 Application issued as United States Patent No. 8,173,637 ("the Handa '637A Patent"). On March 28, 2011, Handa filed

[3] *Id*. at *11.

[4] *Id*. at *13.

United States Application Serial No. 13/073,873 ("the '873 Application"), which claimed the benefit of the filing date of the '356 and '270 Applications. On August 23, 2011, the '873 Application issued as United States Patent No. 8,003,637 ("the Handa '637B Patent").

91. Handa disclosed the '288 and '437 Patents as prior art in the applications that led to the Handa '637A Patent and Handa '637B Patent. By issuing the Handa '637A Patent and Handa '637B Patent despite AstraZeneca's '288 and '479 Patents, the examiner necessarily determined that the claimed compositions in the Handa '637A Patent and Handa '637B Patent were patentably distinct from the compositions disclosed and claimed in AstraZeneca's '288 and '479 Patents.

92. As Handa's own patents explain, HVO is a "hydrophobic" material that is "non-gelling":

> Examples of ***hydrophobic*** materials that can be used to form a ***non-gelling*** or non-swelling controlled release matrix for the atypical antipsychotic drug include beeswax, white wax, emulsifying wax, ***hydrogenated vegetable oil***, hydrogenated castor oil, microcrystalline wax, cetyl alcohol, stearyl alcohol, free wax acids such as stearic acid, esters of wax acids, propylene glycol mono stearate, glycerol mono stearate, carnauba wax, palm wax, candelilla wax, lignite wax, ozokerite, ceresin wax, lardaceine, China wax and mixtures thereof. Other possible rate controlling excipients useful in the present invention include saturated hydrocarbons having from 25 to 31 carbon atoms, saturated alcohols having from 25 to 31 carbon atoms, saturated monocarboxylic acids having from 25 to 31 carbon atoms, esters obtained from said alcohols and monocarboxylic acids which are described in U.S. Pat. No. 6,923,984, incorporated herein by reference.[5]

93. The district court's claim construction in the Seroquel XR Patent Litigation requires that, *inter alia*, the "gelling agent" interact with "water" to "form [] a gel" (*see supra*); accordingly, one of the important characteristics in determining whether a particular compound is a "gelling agent" is whether it is "hydrophilic" (*i.e.*, water loving) or "hydrophobic" (*i.e.*, water hating). This is so because "hydrophobic" compounds such as HVO generally do not

[5] '637A Patent at 6:24-39 (emphasis added).

interact with water. Indeed, the '437 Patent itself indicates that the claimed "gelling agent" must be "hydrophilic": "The term gelling agent as used herein means any substance, ***particularly a hydrophilic substance***, which forms a gel when in contact with water. . . ."[6]

94. Although Handa settled before trial in the Seroquel XR Patent Litigation, evidence and arguments at the trial for the non-settling generics confirm that Handa's non-infringement defense would have prevailed at trial. In opening statements, AstraZeneca's counsel focused on the fact that the Viscarin 209 in Torrent's product was "hydrophilic" and interacts substantially with water:

> Torrent does not use HPMC. Instead, Torrent uses a commercial carrageenan material called Viscarin GP209. Carrageenan, by way of background, is a naturally-occurring polymer, harvested from, believe it or not, seaweed, like FMC's Viscarin GP209 product is a hydrophilic, that is it's water loving, it hydrates and swells in the presence of the water.[7]

95. During the questioning of AstraZeneca's expert regarding Viscarin 209, the hydrophilicity of the compound was a focal point of the examination:

> Q. Can you explain what part of the '437 patent informs you what is contemplated by the word "gel"?
>
> A. Go back to the patent.
>
> Q. I believe it's tab four.
>
> A. Tab four. In the second column is yellow highlighted materials of the term "gelling agent" as used herein means a substance particularly a hydrophilic substance, which forms a gel when in contact with water and thus, includes such substances as, and it gives a long list of substances which are polymers. The gelling agent is preferably hydroxypropylmethylcellulose.
>
> Q. The patent states it's particularly a hydrophilic substance. Can you explain to the Court what a hydrophilic gelling agent is?

[6] '437 Patent at 2:43-45 (emphasis added).

[7] Later-Filer Seroquel XR Patent Litigation Trial Transcript (Oct. 3, 2011) at 8.

A. Hydrophilic comes from hydro, water and philic, loves so it's a material that likes water, has intrinsic positive interAction with water, will tend to hydrate and swell.

Q. So hydrophilic gelling agents will hydrate and swell?

A. They will hydrate and swell. . . .

Q. Now, Dr. Prud'homme, a moment ago when we were looking at the '437 patent, we saw it refers to the use of hydrophilic polymers as gelling agents. Are carrageenans [*i.e.*, the compounds in Viscarin 209] hydrophilic polymers?

A. Yes, they are.

Q. And what happens to these hydrophilic carrageenan polymers when they come in contact with water?

A. Well, they will tend to hydrate and swell. They also tend to gel.[8]

This questioning, like the text in the '437 Patent itself and AstraZeneca's opening statement, highlights why a hydrophobic compound like the HVO in Handa's products was very unlikely to be found to be a "gelling agent" as required by the claims of the '437 Patent. Furthermore, HVO could not have satisfied the requirement for a "gelling agent" under the doctrine of equivalents because HVO is substantially different from the claimed "gelling agent" and further does not satisfy the doctrine of equivalents' function-way-result test.

96. Had Handa not settled with AstraZeneca, Handa would have prevailed on its non- infringement defense. In addition, Handa had other meritorious defenses.

E. AstraZeneca Enters into Unlawful Reverse-Payment Agreements with Handa and Accord

97. On or about September 29, 2011, AstraZeneca and Handa entered into the Handa Non-Compete Agreement. On or about October 5, 2011, AstraZeneca and Accord entered into the Accord Non-Compete Agreement.

[8] *Id*. (Oct. 3, 2011) at 74:7-79:25.

98. Under the terms of the Non-Compete Agreements, Handa and Accord respectively agreed to quit their patent fights and delay their respective generic Seroquel XR launches until November 1, 2016. In exchange for Handa's and Accord's agreements to delay launching, AstraZeneca agreed not to compete with Handa or Accord by launching an authorized generic for the first six months after their launches, *i.e.*, AstraZeneca agreed not to launch an authorized generic until May 1, 2017. The purpose and effect of the Non-Compete Agreements was to prevent AstraZeneca from facing lower-priced generic competition for up to five years and to allow Handa and Accord to sell generic Seroquel XR without competition from authorized generic Seroquel XR for six months after Handa's and Accord's November 1, 2016 generic Seroquel launches, *i.e.*, from November 1, 2016 through April 30, 2017.

99. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90-482. As part of Par's acquisition of Handa's ANDA, Handa assigned the Handa Non-Compete Agreement to Par. As explained above, Par became an active participant and co-conspirator in the pre-existing conspiracy between Handa and AstraZeneca and is jointly and severally liable for all harm flowing from the conspiracy.

100. AstraZeneca always intended to launch an authorized generic to compete with Handa/Par's and Accord's generic Seroquel XR products, as evident from the fact that AstraZeneca actually did so on the first day it was allowed to under the terms of the Non-Compete Agreements. But for the Non-Compete Agreements, AstraZeneca would have launched authorized generic Seroquel XR at the time that Handa/Par and Accord launched, and competed for generic Seroquel XR sales during Handa/Par's and Accord's 180-day exclusivity periods. Instead, because of the Non-Compete Agreements, AstraZeneca waited 180 days after Handa/Par's and Accord's generic Seroquel XR launches to launch competitive authorized generic Seroquel XR.

101. Accord received FDA tentative approval for its ANDA No. 90-0681 on December 14, 2010 and final approval on November 1, 2016. Accord's 400 mg generic Seroquel XR product would have received final approval before November 1, 2016 absent the Accord Non-Compete Agreement. Handa received tentative approval from FDA on December 9, 2010. Par obtained final FDA approval for ANDA No. 90-482 on May 9, 2017, almost exactly the end of its 180-day exclusivity period. Absent the Handa Non-Compete Agreement, Handa/Par's 50 mg, 150 mg, 200 mg and 300 mg strengths of generic Seroquel XR would have received final FDA approval before November 1, 2016. Handa's and Accord's tentative FDA approvals meant that their ANDAs were ready for FDA final approval but for the existence of a patent or regulatory barrier.

102. AstraZeneca provided Handa/Par and Accord with licenses under its '437 Patent, and reverse payments in the form of agreements not to launch authorized generic versions of Handa/Par's and Accord's respective strengths of generic Seroquel XR ("no-AG provisions" or "no-AG promises"). AstraZeneca was motivated to make these reverse payments because it was a preferable alternative to AstraZeneca than risking an adverse ruling on its patent, which would have caused earlier generic Seroquel XR entry.

103. But-for the Non-Compete Agreements, Par/Handa and Accord would have been ready, able, and willing to launch their respective strengths of generic Seroquel XR much earlier. Handa/Par's and Accord's generic Seroquel XR products would have launched upon (1) the conclusion of the 30-month stays; (2) litigation victory by Handa/Par and Accord earlier than November 1, 2016; or (3) a licensed generic Seroquel XR entry date earlier than November 1, 2016 pursuant to agreement(s) with AstraZeneca that did not include unlawful reverse payments from AstraZeneca to induce delay. *See, e.g.*, *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) ("when the parties' settlement

includes a [payment], the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted"); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 751-52 (a reverse payment "is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree").

104. By on or about September 29, 2011, when the Handa Non-Compete Agreement was executed, Seroquel XR was generating nearly a billion dollars per year in revenues for AstraZeneca. A generic launch by Handa and/or Accord after prevailing in the patent litigation – or on an earlier date negotiated without any reverse payments – would have drastically reduced AstraZeneca's profits. Thus, AstraZeneca had enormous incentives to avoid competition from Handa and Accord by entering into the Non-Compete Agreements.

105. The Non-Compete Agreements contained confidentiality provisions precluding the parties to those agreements from disclosing the key terms of the Non-Compete Agreements, including AstraZeneca's covenants not to launch an authorized generic of Seroquel XR during Handa/Par's and Accord's 180-day exclusivity periods to compete with Handa/Par and Accord (the no-AG provisions). Although the parties subsequently made vague public references to their Non-Compete Agreements, they concealed the agreements' anticompetitive purpose and terms. No public reference to the Non-Compete Agreements disclosed that AstraZeneca agreed not to compete with an authorized generic during Handa/Par's or Accord's 180-day exclusivity periods.

106. Nor did the parties' disclosures admit that the Non-Compete Agreements each included an agreed-upon anticompetitive no-authorized-generic provision as a *payment* from AstraZeneca to Handa/Par and to Accord in order to induce Handa/Par and Accord to delay generic Seroquel XR entry until November 1, 2016. Plaintiffs lacked sufficient indication of any *quid pro quo* until AstraZeneca actually launched its authorized generic Seroquel XR on

May 1, 2017, immediately after Handa/Par's and Accord's 180-day exclusivity periods ended. Until that time, Plaintiffs and other purchasers of Seroquel XR had no way of knowing that Handa/Par's and Accord's generic Seroquel XR entry dates were delayed by payments made from AstraZeneca to Handa/Par and Accord in the form of no-authorized generic promises. This was a deliberate concealment.

107. AstraZeneca's decision to delay the launch of its authorized generic Seroquel XR until Handa/Par's and Accord's 180-day exclusivities expired made no economic sense other than as part of no-AG reverse-payment settlements. To the extent that a brand manufacturer decides to launch an AG, the most profitable time to launch the AG is simultaneously with the launch by the first ANDA filer. Thus, it would have been far more profitable for AstraZeneca to have launched authorized generic Seroquel XR immediately upon Handa/Par's and Accord's launches. AstraZeneca only agreed to delay its authorized generic launch until May 1, 2017, 180 days after Handa/Par and Accord launched generic Seroquel XR, as a *quid pro quo* for Handa/Par's and Accord's respective agreements to delay generic Seroquel XR competition until November 1, 2016. As explained below, Plaintiffs had no way of knowing of Defendants' anticompetitive agreements until at least the time when it became clear that AstraZeneca took the plainly irrational path of delaying its corresponding authorized generic Seroquel XR launch.

108. As consideration for Handa/Par's and Accord's agreement to forgo selling generic extended-release quetiapine fumarate in competition with AstraZeneca's branded Seroquel XR for up to five years, AstraZeneca agreed to share with Handa/Par and Accord the monopoly profits from sales of branded Seroquel XR in the form of covenants not to compete with Handa/Par's and Accord's generics with authorized generic Seroquel XR. Instead of competing, which would have resulted in lower prices of both generic and branded Seroquel

XR, AstraZeneca agreed and conspired with Handa/Par and with Accord to maintain the prices of extended-release quetiapine fumarate at supracompetitive levels.

109. The Non-Compete Agreements benefitted Handa/Par and Accord by guaranteeing that they would be the sole generic seller on the market for their respective strengths during their 180-day exclusivity periods, which significantly increased Handa/Par's and Accord's anticipated sales revenues during their exclusivity periods because: (1) Handa/Par and Accord would capture all of the sales that would otherwise have gone to competing authorized generic Seroquel XR, and (2) Handa/Par and Accord would be able to charge significantly higher prices for their generic Seroquel XR products without price competition from competing authorized generic Seroquel XR.

110. A brand company's launch of a competing authorized generic is extremely costly to any first-filer generic, such as Handa/Par and Accord, because the authorized generic erodes the first-filer's share of the overall generic volume *and* pushes down generic prices. The authorized generic also cuts into the first-filer's long-term "first mover advantage," *i.e.*, the continuing market advantage that can accrue to the first entrant. As the FTC noted in a June 2009 report on authorized generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [authorized generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [authorized generic]." Thus, AstraZeneca's covenants not to launch authorized generic Seroquel XR during Handa/Par's and Accord's exclusivity periods were extremely valuable to Handa/Par and Accord.

111. In addition, AstraZeneca sacrificed profits through its agreements not to launch authorized generics of Handa/Par's and Accord's respective strengths of generic Seroquel XR. Absent the unlawful Non-Compete Agreements, it would have made economic sense for

AstraZeneca to launch authorized generics during Handa/Par's and Accord's 180-day marketing exclusivity periods so that AstraZeneca would retain some portion of the sales that Handa/Par's and Accord's less expensive generics would otherwise capture.

112. As alleged above, an authorized generic typically captures approximately 50% of the generic unit sales during the first 180-days of generic marketing. Thus, AstraZeneca's promise not to launch an AG of Seroquel XR (the no-AG provision) constituted very large payments to Handa/Par and Accord.

113. Specifically, U.S. sales of Seroquel XR for the four dosage strengths for which Par was the first-filer (the 50 mg, 150 mg, 200 mg and 300 mg strengths) were, and were expected to be, approximately $911 million for the 12 months ending September 30, 2016. Thus, Defendants could assume that 6 months (or half a year) of brand sales (the duration of AstraZeneca's covenant not to launch an authorized generic) would generate revenue of approximately $455.5 million (half of AstraZeneca's $911 million in annual Seroquel XR revenue.

114. In the pharmaceutical industry, a generic typically takes 80% (or more) of the brand sales over the first six months following generic entry. Thus, approximately $364.4 million worth of brand sales would be converted to the generic ($455.5 million * 0.8) during the period of Handa/Par's 180-day exclusivity (the duration of AstraZeneca's covenant not to launch an authorized generic). With only one generic on the market, the generic is typically priced at 70% of the brand, which would result in generic sales of approximately $255.08 million ($364.4 million * 0.7). Thus, the generic Seroquel XR sales revenue that would have reasonably been anticipated by Handa/Par during the 180-day exclusivity period without competition from an AG would be approximately $255.08 million.

115. Handa/Par's expectations would have differed dramatically had AstraZeneca not promised to refrain from competing with authorized generic Seroquel XR. According to an FDA study of the effects of additional generic competitors on the generic price, the entry of a second generic drives the average generic price down to 50% of the brand price or less. Thus, while the brand would still lose 80% of six months of sales, or $364.4 million, the corresponding value of the generic sales would only be $182.2 million ($364.4 million * 0.5). And, Handa/Par would expect to split those sales evenly with AstraZeneca's authorized generic. Thus, without the no-AG promise in the Handa Non- Compete Agreement, Handa/Par's sales of generic Seroquel XR during the first 6 months would be expected to be approximately $91.1 million ($182.2 million * 0.5).

116. As a result, the expected value at the time of the Handa Non-Compete Agreement to Handa/Par of the no-AG provision versus facing competition from an AG would have been as much as approximately $163.98 million, the difference between the amount Handa/Par would reasonably expect to earn as the only generic seller on the market for 180 days following launch and the amount it would reasonably expect to earn if it faced competition from an AG during this 180-day period ($255.08 million - $91.1 million). Thus, AstraZeneca's agreement not to launch an AG for 6 months following Handa/Par's generic launch was a payment to Handa/Par of as much as $163.98 million. The no-AG promise to Handa/Par was tantamount to AstraZeneca handing this amount to Handa/Par in cash.

117. The same math and reasoning apply to Accord. Specifically, in exchange for Accord's commitment not to launch its generic 400 mg strength Seroquel XR until November 1, 2016, AstraZeneca promised Accord that it would not launch an authorized generic version of 400 mg strength Seroquel XR until May 1, 2017. AstraZeneca's sales of the 400 mg strength of Seroquel XR in 2015 (the last full calendar year before generic Seroquel XR entry)

were, and were expected to be, approximately $421 million. Using the same math as used for Handa/Par, the promise from AstraZeneca to Accord to not compete during Accord's 180-day exclusivity period was worth approximately $75.78 million.[9]

118. AstraZeneca often competes with first-filers by launching authorized generics. The FTC has found that, in the time period from 2001 to 2008, only four companies launched more authorized generics than AstraZeneca:[10]

[9] Specifically, Accord's revenues absent competition from an AG would be expected to be $421 million*.5 *.8 *.7, or $117.88 million. Accord's revenues if it faced competition from an AG would be expected to be $421 million*.5*.8*.5*.5, or $42.1 million. The difference is $75.78 million ($117.88 million - $42.1 million).

[10] FTC, Authorized Generic Drugs at 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").

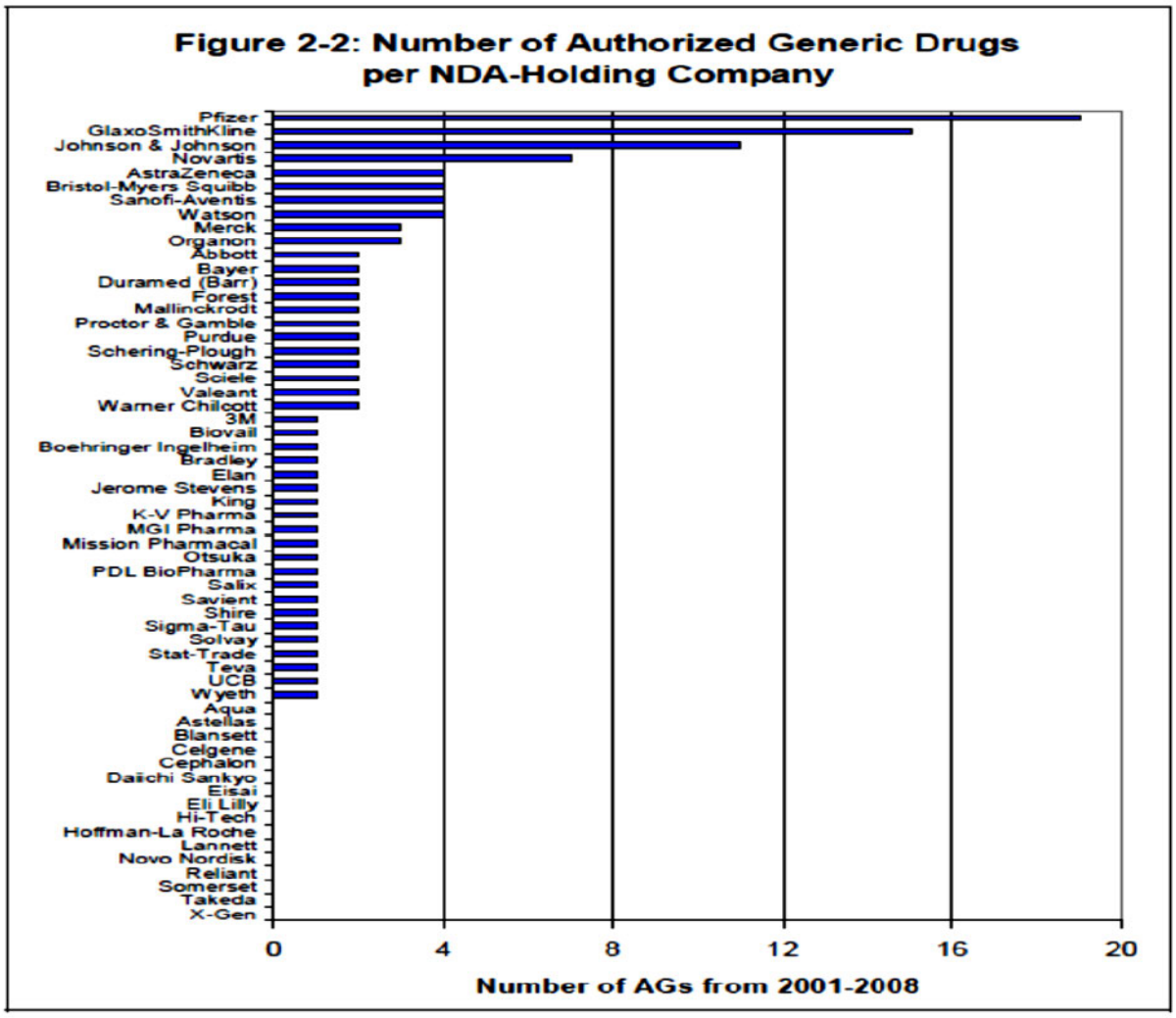
Figure 2-2: Number of Authorized Generic Drugs per NDA-Holding Company
Pfizer
GlaxoSmithKline
Johnson & Johnson
Novartis
AstraZeneca
Bristol-Myers Squibb
Sanofi-Aventis
Watson
Merck
Organon
Abbott
Bayer
Duramed (Barr)
Forest
Mallinckrodt
Proctor & Gamble
Purdue
Schering-Plough
Schwarz
Sciele
Valeant
Warner Chilcott
3M
Biovail
Boehringer Ingelheim
Bradley
Elan
Jerome Stevens
King
K-V Pharma
MGI Pharma
Mission Pharmacal
Otsuka
PDL BioPharma
Salix
Savient
Shire
Sigma-Tau
Solvay
Stat-Trade
Teva
UCB
Wyeth
Aqua
Astellas
Blansett
Celgene
Cephalon
Daiichi Sankyo
Eisai
Eli Lilly
Hi-Tech
Hoffman-La Roche
Lannett
Novo Nordisk
Reliant
Somerset
Takeda
X-Gen
0
4
8
12
16
20
Number of AGs from 2001-2008

119. AstraZeneca has launched authorized generics with respect to at least the following branded drugs: Accolate, Toprol-XL, Novaldex, Entocort EC, Pulmicort, Atacand, Plendil, Prilosec, and Nexium.

120. It is economically rational for a brand manufacturer that intends to compete for generic sales by launching an authorized generic to do so contemporaneously with the first ANDA filer's launch. This is because, during the first-filer's 180-day exclusivity, the only possible competitors for generic sales are the first-filer and the brand's authorized generic. No later-filing generic can launch during this time. As the Third Circuit observed, "Absent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand." *King Drug*, 791 F.3d at 405.

121. Thus, it would have been economically rational for AstraZeneca to have launched authorized generic Seroquel XR contemporaneously with market entry by Handa/Par and Accord instead of *after* Handa/Par's and Accord's 180-day exclusivity periods. In the absence of the anticompetitive Non-Compete Agreements, AstraZeneca would have done so. Specifically, absent the Handa Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 50 mg, 150 mg, 200 mg and 300 mg strengths contemporaneous with Handa/Par's launch of generic Seroquel SR in these same strengths. Absent the Accord Non- Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 400 mg strength contemporaneous with Accord's launch of generic Seroquel XR in the 400 mg strength.

122. Conversely, if there were no agreements preventing AstraZeneca from launching immediately upon Handa/Par's and Accord's launches, AstraZeneca's delay of its authorized generic Seroquel XR until Handa/Par's and Accord's 180-day exclusivity periods expired would have been economically irrational. There was no economically rational reason for

AstraZeneca to delay its launch of AG Seroquel XR launches and competition with Handa/Par and Accord during Handa/Par's and Accord's 180-day exclusivity periods. During the 180-day exclusivity period, AstraZeneca would only have to compete with a single generic competitor in each strength. After expiry of Handa/Par's and Accord's 180-day exclusivity periods, other generics could and would launch and AstraZeneca's AG would have to compete with those other generics too. Thus, it only made sense for AstraZeneca to forgo its authorized generic launch during Handa/Par's and Accord's 180-day exclusivity periods as part of anticompetitive market-allocation or output-restriction agreements to compensate Handa/Par and Accord for delaying generic Seroquel XR competition.

123. The payments flowing from AstraZeneca to Handa/Par and to Accord via the Non-Compete Agreements' no-AG provisions had a cash value of as much as approximately $163.98 million to Handa/Par and $75.78 million to Accord. AstraZeneca intended these payments to induce Handa/Par and Accord to delay entry into the market for Seroquel XR and its generic equivalents in return for a share of AstraZeneca's monopoly profits. This was a *per se* illegal naked market allocation or output restriction agreement. But even under the rule of reason, the reverse payments from AstraZeneca to Handa/Par and Accord are unjustified, and Defendants had no procompetitive justification or other legitimate explanation for the payments. There is no conceivable procompetitive justification for a covenant to delay the launch of authorized generics.

124. Any agreement resolving AstraZeneca's patent infringement claim without the unlawful no-AG agreement would have resulted in far less (or no) delay of Handa/Par's and Accord's generic Seroquel XR, more robust generic competition, and lower generic prices. But for the Non-Compete Agreements, Handa/Par and Accord would have launched their respective strengths of generic Seroquel XR earlier: at risk, following a patent litigation victory, or

pursuant to a negotiated entry date as part of an agreement that did not include reverse payments.[11] At the same time, AstraZeneca would have competed for generic Seroquel XR sales by immediately launching authorized generic Seroquel XR instead of waiting to launch its authorized generic Seroquel XR for 6 months following Handa/Par's and Accord's generic launches.

125. Had Handa/Par and Accord launched their respective strengths of generic Seroquel XR earlier, those Later-Filing Generics would have launched earlier as well. But for the bottleneck of generic competition caused by the Non-Compete Agreements, one or more Later-Filing Generics would have launched earlier, along with Handa/Par's generic, Accord's generic, and the authorized generic, lowering generic Seroquel XR prices even further.

126. Handa/Par and Accord did not refrain from launching earlier than November 1, 2016 because of the potential risk that they would infringe the '437 Patent. Rather, Handa/Par's and Accord's generic launches were delayed by the anticompetitive Non-Compete Agreements, just as Defendants understood and intended. In addition, Handa/Par and Accord, as the first ANDA filers for their respective strengths, had 180 days of regulatory exclusivity for those strengths during which no subsequent filer could launch an ANDA version of Seroquel XR. Thus, Handa/Par, Accord and AstraZeneca all recognized that delaying Handa/Par's and Accord's generic launches in exchange for no-AG covenants would benefit each of them. AstraZeneca would benefit by continuing to charge monopoly prices for Seroquel XR almost until expiry of the '437 Patent despite the patent's weakness. Handa/Par and Accord benefitted

[11] As the Supreme Court has stated, brand and generic companies can settle without reverse payments. "They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *FTC v. Actavis*, 570 U.S. 136, 158 (2013).

by securing no-AG promises allowing them to be free from AG competition for the first six months after their delayed generic Seroquel XR launches.

127. According to information available publicly through the FDA, in addition to first-filers Handa/Par and Accord, at least 12 additional companies filed ANDAs to sell generic Seroquel XR:

Application No.	Company
209497	Alignscience Pharma Inc.
090757	Anchen
207655	Aurobindo Pharma Ltd.
202939	IntellipharmaCeutics Corp.
204203	Lupin Ltd.
204253	Macleods Pharmaceuticals
202228	Mylan
208947	Novast Laboratories
201424	Osmotica
206260	Pharmadax Inc.
209635	Sciegen Pharmaceuticals
202377	Torrent

128. According to information available publicly through the FDA, many of these entities received final approval on or around the end of Handa/Par's and Accord's actual 180-day exclusivity periods. These included Pharmadax Inc., IntellipharmaCeutics Corp., Accord (as to the 150 mg, 200 mg and 300 mg strengths), Par (as to the 400 mg strength) and Lupin Ltd. These approvals would have been granted earlier if Handa/Par's and Accord's 180-day exclusivity periods had been triggered (and elapsed) earlier as a result of Handa/Par and Accord launching generic Seroquel XR earlier, which would have occurred absent AstraZeneca's payments to Handa/Par and to Accord to delay competition (*i.e.*, absent AstraZeneca's no-AG promises).

129. But for the Non-Compete Agreements, generic competition for Seroquel XR, including competition from authorized generic Seroquel XR, would have occurred earlier, and

prices for extended-release quetiapine fumarate would have been lower. Generic versions of Seroquel XR would have become available much earlier – through a Handa and/or Accord patent victory, an at-risk launch, or agreement(s) that did not include unlawful payments for delay. Under any such scenario, Plaintiffs would have paid lower prices for Seroquel XR and its generic equivalents. Defendants, by their conduct, have injured Plaintiffs by causing them to pay millions of dollars in overcharges on their purchases of extended-release quetiapine fumarate.

VI. INTERSTATE COMMERCE

130. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VII. CLAIM ACCRUAL AND TOLLING

131. By virtue of their assignments, Plaintiffs are absent class members in the putative direct purchaser class Action filed by J.M. Smith Corporation d/b/a Smith Drug Company. *See J.M. Smith Corp. v. AstraZeneca Pharms. L.P. et al.*, Case No. 1:19-cv-7233 (S.D.N.Y.) (filed Aug. 2, 2019). Plaintiffs have a cause of Action each time they or their assignors purchased Seroquel XR or generic Seroquel XR at a price higher than would have been paid absent Defendants' unlawful conduct. The *J.M. Smith* complaint was filed on August 2, 2019 and tolled the applicable statute of limitations as to all putative class members. Thus, at a minimum, Plaintiffs' Complaint is timely as to all claims for overcharges based on purchases of branded or generic Seroquel XR that occurred during the four years prior to the filing date of the *J.M. Smith* complaint (*i.e.*, beginning on August 3, 2015).

132. Plaintiffs' claims based on purchases prior to August 3, 2015 are also timely because Defendants fraudulently concealed their unlawful conduct and Plaintiffs did not and

could not have discovered that conduct by the exercise of reasonable diligence prior to May 2017, thereby tolling the statute. The doctrine of fraudulent concealment applies because (1) Defendants affirmatively concealed the existence of this cause of Action, (2) Plaintiffs remained in ignorance of this cause of Action until on or about May 1, 2017, and (3) Plaintiffs' continuing ignorance was not attributable to lack of diligence on their part.

133. Specifically, Defendants concealed from Plaintiffs the terms of the Non-Compete Agreements pursuant to which AstraZeneca agreed not to launch authorized generic Seroquel XR during Handa/Par's and Accord's 180-day exclusivity periods – a common form of "pay-for-delay." Even when limited information about the Non-Compete Agreements was made available in SEC filings or press releases, the key illegal terms, the no-AG promises, were not disclosed. No publicly available information states that the Non-Compete Agreements precluded AstraZeneca from launching authorized generic Seroquel XR for 180 days following Handa/Par's and Accord's generic launches.

134. Moreover, the Non-Compete Agreements were inherently self-concealing. Had their unlawful provisions not been kept secret, they would not have succeeded, because of, *inter alia*, the availability of injunctive relief to prevent their performance.

135. Plaintiffs remained in ignorance of this cause of Action until approximately May 2017, which is less than four years prior to the filing of the *J.M. Smith* Action or this Action, and Plaintiffs' continuing ignorance was not attributable to a lack of diligence on their part.

136. Specifically, Plaintiffs had insufficient knowledge to file an antitrust claim until at least May 1, 2017, when AstraZeneca launched an authorized generic Seroquel XR in all strengths simultaneously with the expiration of Handa/Par's and Accord's 180-day

exclusivities. Prior to that time Plaintiffs lacked any actual knowledge of an antitrust violation and could not have discovered the violation through the exercise of reasonable diligence.

137. As a result of Defendants' fraudulent concealment, the four-year statute of limitation applicable to Plaintiffs' claims was tolled and Plaintiffs' claims are timely.

VIII. ANTICOMPETITIVE EFFECT

138. The Non-Compete Agreements enabled Defendants to: (a) prevent and delay until November 1, 2016 the entry of less-expensive generic versions of Seroquel XR products in the United States; (b) fix, raise, maintain, or stabilize the price of Seroquel XR products; (c) allocate to AstraZeneca 100% of the U.S. market for Seroquel XR and its generic equivalents until November 1, 2016; (d) allocate to Handa/Par 100% of U.S. sales of the 50 mg, 150 mg, 200 mg and 300 mg strengths of generic Seroquel XR from November 1, 2016 through April 30, 2017; and (e) allocate to Accord 100% of U.S. sales of the 400 mg strength of generic Seroquel XR from November 1, 2016 through April 30, 2017.

139. Par launched generic 50 mg, 150 mg, 200 mg, and 300 mg strengths of Seroquel XR on November 1, 2016, thereby triggering its 180-day exclusivity period as to those strengths of generic Seroquel XR. Accord launched a generic version of the 400 mg strength of Seroquel XR that same day, thereby triggering its 180-day exclusivity period as to the 400 mg strength of generic Seroquel XR. At least three Later-Filing Generics received final approval on or about May 9, 2017, shortly following the expiry of Par's and Accord's 180-day exclusivity periods. AstraZeneca launched authorized generic Seroquel XR for all strengths (50 mg, 150 mg, 200 mg, 300 mg, and 400 mg) upon expiration of the 180-day exclusivity period.

140. But for the unlawful Handa Non-Compete Agreement, Handa/Par would have begun selling a less expensive generic version of the 50 mg, 150 mg, 200 mg and 300 mg strengths of Seroquel XR much earlier than November 1, 2016. Such sales would have

occurred via market entry by Handa/Par upon a Handa/Par litigation victory, at risk, or via a licensed entry in a settlement with AstraZeneca that did not include a no-AG provision or any other unlawful reverse payments from AstraZeneca to Handa/Par. Contemporaneously with market entry by Handa/Par, AstraZeneca would have begun selling lower-priced authorized generic Seroquel XR in the 50 mg, 150 mg, 200 mg and 300 mg strengths in direct competition with the Handa/Par's generic. Other generic manufacturers would have launched generic Seroquel XR in the 50 mg, 150 mg, 200 mg and 300 mg strengths approximately 180 days after Handa/Par's launch.

141. Similarly, but for the illegal Accord Non-Compete Agreement, Accord would have begun selling a lower-price generic version of Seroquel XR in the 400 mg strength earlier than November 1, 2016. Such sales would have occurred via market entry by Accord following a litigation victory, at-risk, or via a licensed entry in a settlement with AstraZeneca that did not include a no-AG provision or any other unlawful reverse payments from AstraZeneca to Accord. Contemporaneously with market entry by Accord, AstraZeneca would have begun selling lower-priced authorized generic Seroquel XR in the 400 mg strength in direct competition with Accord's generic. Other generic manufacturers would have launched generic Seroquel XR in the 400 mg strength approximately 180 days after Accord's generic launch.

142. An increasingly competitive market for Seroquel XR and its generic equivalents, with lower prices, would have thereafter emerged as additional generic Seroquel XR products entered the market.

143. Defendants' unlawful concerted Action has (a) delayed and suppressed the sale of generic Seroquel XR in the United States, (b) enabled AstraZeneca to sell Seroquel XR at artificially inflated, supracompetitive prices, (c) enabled Handa/Par and Accord to sell generic

Seroquel XR, at artificially inflated, supracompetitive prices, and (d) caused Plaintiffs to pay supracompetitive prices for extended-release quetiapine fumarate tablets.

144. Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

145. During the relevant period, Plaintiffs and their assignors purchased substantial quantities of brand and generic Seroquel XR at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiffs (and their assignors) were compelled to pay, and did pay, artificially inflated prices for their requirements of extended-release quetiapine fumarate. Those prices were substantially greater than the prices that Plaintiffs would have paid absent the illegal conduct alleged herein, because: (1) the price of Seroquel XR was artificially inflated by Defendants' illegal conduct, and (2) Plaintiffs were deprived of the opportunity to purchase lower-priced generic versions of Seroquel XR sooner, which they would have done had they had the opportunity. In addition, when generic versions of Seroquel XR were finally available, prices of generic Seroquel XR were higher than they would have been absent Defendants' unlawful conduct, and Plaintiffs have therefore incurred overcharges on their purchases of generic Seroquel XR as well.

146. As a direct consequence of Defendants' antitrust violations, Plaintiffs have sustained substantial loss and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

X. MONOPOLY POWER AND MARKET DEFINITION

147. At all relevant times prior to November 1, 2016, AstraZeneca had and maintained monopoly power in the market for Seroquel XR and its generic equivalents because it had the power to maintain the price of extended-release quetiapine fumarate at

supracompetitive levels without losing enough sales to make the supracompetitive price unprofitable.

148. Direct proof exists that AstraZeneca had monopoly power over the price of extended-release quetiapine fumarate. Such direct evidence includes, among other things, the abnormally high price-cost margins enjoyed by AstraZeneca prior to entry of generic Seroquel XR and AstraZeneca's ability to profitably maintain the price of Seroquel XR well above competitive levels.

149. Manufacturers attempt to differentiate brand name drugs like Seroquel XR based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Seroquel XR. This price-insensitivity is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs, and the existence of other drugs within its therapeutic class did not constrain the price of Seroquel XR to its competitive level absent AstraZeneca's reverse payments. As a result of the market imperfections described above, only AB-rated generic Seroquel XR constrains the price of Seroquel XR to its competitive level.

150. Other drugs that are not AB-rated to Seroquel XR cannot be substituted automatically for Seroquel XR by pharmacists, do not exhibit substantial cross-price elasticity of demand with Seroquel XR, and thus are not economic substitutes for, nor reasonably interchangeable with, Seroquel XR.

151. Other products are not substitutes for Seroquel XR or its generic equivalents, and the existence of other products designed to treat depression, bipolar disorder, schizophrenia, or other illnesses treated by Seroquel XR have not constrained AstraZeneca's pricing of Seroquel

XR to the competitive level. AstraZeneca has never lowered the price of Seroquel XR in response to the pricing of other branded or generic drugs.

152. AstraZeneca needed to control only the sales of Seroquel XR and its generic equivalents, and no other products, in order to maintain the price of Seroquel XR profitably at supracompetitive prices. Only the market entry of a competing, generic version of Seroquel XR would render AstraZeneca unable to profitably maintain its prices of Seroquel XR without losing substantial sales.

153. To the extent Plaintiffs are required to prove monopoly power circumstantially by first defining a relevant product market, the relevant market is Seroquel XR (in all its forms and dosage strengths) and AB-rated generic Seroquel XR (in all its forms and dosage strengths). The relevant geographic market is the United States.

154. AstraZeneca's anticompetitive reverse payments to Handa/Par and to Accord demonstrate that AstraZeneca enjoyed market and/or monopoly power with respect to extended- release quetiapine fumarate tablets.

155. A small but significant non-transitory price increase in the price of Seroquel XR above its competitive level would not cause a loss of sales sufficient to make the price increase unprofitable.

156. At all relevant times, high barriers to entry into the relevant market for Seroquel XR and its generic equivalents existed, including patent and other regulatory protections, and high costs of entry and expansion.

157. During the relevant period, Defendants' conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by the delay of lower cost generic Seroquel XR.

158. AstraZeneca has maintained and exercised the power to exclude and restrict competition to Seroquel XR and its AB-rated generics.

159. The relevant geographic market is the United States.

160. At all relevant times prior to November 1, 2016, AstraZeneca's market share in the relevant market was 100%, implying substantial monopoly power.

XI. CLAIMS FOR RELIEF

CLAIM ONE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(DEFENDANTS ASTRAZENECA, HANDA AND PAR)

161. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 160 above. This claim is asserted against Defendants AstraZeneca, Handa and Par.

162. Defendants AstraZeneca, Handa and Par have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

163. On or about September 29, 2011, when the Handa Non-Compete Agreement was executed, and possibly prior to the formal execution thereof, Defendants entered into an illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to make a large reverse payment to Handa/Par in exchange for Handa/Par's agreement to delay its 50 mg, 150 mg, 200 mg and 300 mg (the "Handa/Par Strengths") generic Seroquel XR to the market for up to 5 years. The purpose and effect of the Handa Non-Compete Agreement was to: (a) allocate to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate for the Handa/Par Strengths until November 1, 2016; (b) delay the availability of generic Seroquel XR in the Handa/Par Strengths in the United States, thereby protecting Seroquel XR from any generic competition in those strengths until November 1, 2016; (c) delay the entry of AstraZeneca's authorized generic in the Handa/Par Strengths until May 1, 2017, 180 days after

Handa/Par's generic entry in the Handa/Par Strengths, and allocate to Handa/Par 100% of U.S. sales of generic extended-release quetiapine fumarate for the Handa/Par Strengths prior to that time; and (d) fix and maintain, at supracompetitive levels, the price that Plaintiffs paid for extended-release quetiapine fumarate in the Handa/Par Strengths.

164. Par joined the illegal contract, combination and conspiracy in restraint of trade when Par acquired Handa's ANDA and Handa assigned to Par the Handa Non- Compete Agreement. Par then further participated in the illegal contract, combination and conspiracy in restraint of trade by performing and abiding by the unlawful Handa Non-Compete Agreement, by selling generic Seroquel at supracompetitive prices, and by dividing the ill-gotten gains with Handa.

165. Defendants AstraZeneca, Handa and Par are jointly and severally liable for the injury to Plaintiffs caused by their unlawful conspiracy.

166. There is and was no legitimate, procompetitive justification for the payment from AstraZeneca to Handa/Par that outweighs its harmful effect. Even if there were some conceivable justification, the payment was neither necessary to achieve it, nor the least restrictive means of achieving it.

167. As a direct, proximate, foreseeable, and intended result of the unlawful conspiracy in restraint of trade, as alleged herein, Plaintiffs were harmed and suffered overcharge damages on purchases of branded and generic Seroquel XR.

CLAIM TWO
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(DEFENDANTS ASTRAZENECA, HANDA AND PAR)

168. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 160 above. This claim is asserted against Defendants AstraZeneca, Handa and Par.

169. At all relevant times prior to November 1, 2016, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

170. Through the Handa Non-Compete Agreement, AstraZeneca, Handa and Par conspired to unlawfully maintain AstraZeneca's monopoly power in the relevant market by agreeing to block and delay market entry of generic Seroquel XR in the Handa/Par Strengths.

171. The Handa Non-Compete Agreement (a) allocated to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate in the Handa/Par Strengths until November 1, 2016; (b) delayed the availability of generic versions of Seroquel XR in the Handa/Par Strengths in the United States, thereby protecting Seroquel XR in the Handa/Par Strengths from any generic competition until November 1, 2016; (c) delayed the entry of AstraZeneca's authorized generic in the Handa/Par Strengths until May 1, 2017, 180 days after Handa/Par's generic entry in the Handa/Par Strengths, and allocated to Handa/Par 100% of the U.S. sales of generic extended-release quetiapine fumarate in the Handa/Par Strengths prior to that time; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for extended-release quetiapine fumarate in the Handa/Par Strengths.

172. The goal, purpose and/or effect of the Handa Non-Compete Agreement was to maintain, enhance, and extend AstraZeneca's monopoly power, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Handa Non-Compete Agreement was intended to and did prevent and/or delay generic competition to Seroquel XR in the Handa/Par Strengths and enabled AstraZeneca to continue charging supracompetitive prices for Seroquel XR in the Handa/Par Strengths without a substantial loss of sales.

173. Defendants knowingly and intentionally conspired to maintain, enhance, and extend AstraZeneca's monopoly power in the relevant market.

174. Defendants specifically intended that the Handa Non-Compete Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injure Plaintiffs thereby.

175. Defendants each committed at least one overt act in furtherance of the conspiracy.

176. As a direct, proximate, foreseeable, and intended result of Defendants' concerted monopolistic conduct, as alleged herein, AstraZeneca unlawfully maintained, enhanced, and extended its monopoly power and Plaintiffs suffered overcharge damages on purchases of branded and generic Seroquel XR.

CLAIM THREE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(DEFENDANTS ASTRAZENECA AND ACCORD)

177. Plaintiff incorporate by reference the allegations set forth in paragraphs 1 through 160 above. This claim is asserted against Defendants AstraZeneca and Accord.

178. Defendants AstraZeneca and Accord have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

179. On or about October 5, 2011, when the Accord Non-Compete Agreement was executed, and possibly prior to the formal execution thereof, AstraZeneca entered into an illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to make a large reverse payment to Accord in exchange for Accord's agreement to delay its 400 mg strength generic Seroquel XR for up to 5 years, the purpose and effect of which was to: (a) allocate to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate for the

400 mg strength until November 1, 2016; (b) delay the availability of generic Seroquel XR in the 400 mg strength in the United States, thereby protecting Seroquel XR from any generic competition until November 1, 2016; (c) delay the entry of AstraZeneca's authorized generic in the 400 mg strength until May 1, 2017, 180 days after Accord's entry with generic Seroquel XR in the 400 mg strength, and allocate to Accord 100% of U.S. sales of generic extended-release quetiapine fumarate for the 400 mg strength prior to that time; and (d) fix and maintain, at supracompetitive levels, the price Plaintiffs paid for extended-release quetiapine fumarate in the 400 mg strength.

180. AstraZeneca and Accord are jointly and severally liable for the injuries to Plaintiffs caused by the Accord Non-Compete Agreement.

181. There is and was no legitimate, procompetitive justification for the large payment from AstraZeneca to Accord that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was neither necessary to achieve it, nor the least restrictive means of achieving it.

182. As a direct, proximate, foreseeable, and intended result of the unlawful Accord Non-Compete Agreement, as alleged herein, Plaintiffs suffered overcharge damages on purchases of branded and generic Seroquel XR.

CLAIM FOUR
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(DEFENDANTS ASTRAZENECA AND ACCORD)

183. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 160 above. This claim is asserted against Defendants AstraZeneca and Accord.

184. At all relevant times prior to November 1, 2016, AstraZeneca possessed substantial market power (i.e., monopoly power) in the relevant market. AstraZeneca possessed

the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

185. Through the Accord Non-Compete Agreement, AstraZeneca conspired with Accord to maintain, enhance, and extend AstraZeneca's monopoly power in the relevant market by agreeing to block and delay market entry of generic Seroquel XR in the 400 mg strength.

186. The Accord Non-Compete Agreement (a) allocated to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate in the 400 mg strength until November 1, 2016; (b) delayed the availability of generic versions of Seroquel XR in the 400 mg strength in the United States thereby protecting Seroquel XR in the 400 mg strength from any generic competition until November 1, 2016; (c) delayed the entry of AstraZeneca's authorized generic in the 400 mg strength until May 1, 2017, 180 days after Accord's generic entry in the 400 mg strength, and allocated 100% of U.S. sales of generic extended-release quetiapine fumarate in the 400 mg strength to Accord prior to that time; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for extended-release quetiapine fumarate in the 400 mg strength.

187. The goal, purpose and/or effect of the Accord Non-Compete Agreement was to maintain, enhance, and extend AstraZeneca's monopoly power, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Accord Non-Compete Agreement was intended to and did prevent and/or delay generic competition to Seroquel XR in the 400 mg strength and enabled AstraZeneca to continue charging supracompetitive prices for Seroquel XR in the 400 mg strength until November 1, 2016 without a substantial loss of sales.

188. AstraZeneca knowingly and intentionally conspired with Accord to maintain, enhance, and extend AstraZeneca's monopoly power in the relevant market.

189. AstraZeneca specifically intended that the Accord Non-Compete Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiffs thereby.

190. As a direct, proximate, foreseeable, and intended result of the Accord Non-Compete Agreement, as alleged herein, AstraZeneca unlawfully maintained, enhanced, and extended its monopoly power and Plaintiffs suffered overcharge damages on purchases of branded and generic Seroquel XR.

CLAIM FIVE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(DEFENDANT ASTRAZENECA)

191. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 160 above. This claim is asserted against Defendant AstraZeneca.

192. At all relevant times prior to November 1, 2016, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

193. By entering into the Handa Non-Compete Agreement and the Accord Non-Compete Agreement, AstraZeneca willfully and intentionally maintained, enhanced, and extended its monopoly power using restrictive or exclusionary conduct, rather than by competing on the merits. Specifically, AstraZeneca (a) allocated to itself 100% of the market for extended-release quetiapine fumarate in all strengths in the United States until November 1, 2016; (b) delayed the availability of generic versions of Seroquel XR in all strengths in the United States, thereby protecting Seroquel XR in all strengths from any generic competition until November 1, 2016; (c) delayed the entry of its authorized generic in all strengths until 180 days after Par's and Accord's entry with generic Seroquel XR products, approximately May 1,

2017, and allocated 100% of U.S. sales of generic extended-release quetiapine fumarate in the Handa/Par Strengths to Handa/Par and 100% of U.S. sales of generic extended-release quetiapine fumarate in the 400 mg strength to Accord prior to May 1, 2017; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiffs paid for extended-release quetiapine fumarate.

194. It was AstraZeneca's conscious objective to further its dominance in the relevant market by and through the anticompetitive conduct alleged herein.

195. AstraZeneca's anticompetitive conduct substantially harmed competition in the relevant market.

196. As a direct, proximate, foreseeable, and intended result of AstraZeneca's illegal and monopolistic conduct, AstraZeneca unlawfully maintained, enhanced, and extended its monopoly power, and Plaintiffs suffered overcharges on purchases of branded and generic Seroquel XR.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged above is in violation of sections 1 and 2 of the Sherman Act;

B. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled as provided by law;

C. An award of Plaintiffs' costs and reasonable attorneys' fees; and

D. Such other and further relief as the Court may deem just and proper.

XIII. JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: October 30, 2019

Respectfully submitted,

/s/ *Scott E. Perwin*

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